REMARKS

Favorable reconsideration and allowance of this application are requested.

1. Response to 35 USC §112 Issue

Claim 16 was rejected under 35 USC 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. By way of the amendment instructions above, the parenthetical expression has been eliminated from claim 16 so as to obviate this rejection.

2. Response to Art-Based Rejections

Claims 1-4, 6-10, 15, 16, 19, 27, 35, 39 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. U.S. Patent 6,344,209 in view of Bell et al. U.S. Patent Appln. Pub. 2002/0055143 A1. Reconsideration is requested.

Claim 1 states:

> A composition for the controlled release of an active agent comprising an active agent and a matrix polymer dispersed throughout a matrix having a coating wherein said matrix is the hydration reaction product of an aqueous mixture comprised of:
>
> an inorganic compound capable of undergoing hydration and/or crystallization,
>
> a matrix polymer,
>
> wherein said inorganic compound of said matrix becomes a solid by hydration and/or crystallization.

Saito relates to an apatite-coated solid composition. Preformed apatite particles and a medicinal are simply mixed with a polyester. It does not relate to a composition where the active agents are "dispersed *throughout a matrix* **having a coating** " and wherein the matrix is *"the hydration reaction product of an aqueous mixture comprised of: an inorganic compound capable of undergoing hydration and/or crystallization*, a matrix polymer, wherein said inorganic compound of said matrix becomes a solid by hydration and/or crystallization (emphasis added)."

Bell relates to a bone precursor composition comprising a calcium cement which is suitable for injection, wherein said calcium cement includes monobasic calcium phosphate monohydrate and beta–tricalcium phosphate.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the glucosaminoglycans and polysaccharides of Bell within the "coated solid compositions" of Saito. However as noted above, the "coated solid compositions" of Saito are very different from the matrix compositions of the subject invention and combining Saito and Bell would in no way arrive at the compositions of the subject invention. There is no discussion in these references of a sustained release matrix having a coating. In direct contrast, the subject drug delivery matrix according to the presently claimed invention is coated after manufacture in order to modulate release profile.

Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. U.S. Patent 6,344,209 in view of Bell et al. U.S. Patent Appln. Pub. 2002/0055143 A1, and further in view of Petersen et al U.S. Patent Appln. Pub. 2002/0071827 A1. Reconsideration is requested.

Claim 18 is substantively the same as pending claim 1 but specifies that the coating is HPMC.

As noted above, Saito relates to an apatite-coated solid composition. It does not relate to a composition where the active agents are "*dispersed throughout a matrix* **having a coating** " and which is "*the hydration reaction product of an aqueous mixture comprised of: an inorganic compound capable of undergoing hydration and/or crystallization*, a matrix polymer, wherein said inorganic compound of said matrix becomes a solid by hydration and/or crystallization (emphasis added)."

Bell relates to a bone precursor composition comprising a calcium cement which is suitable for injection, wherein said calcium cement includes monobasic calcium phosphate monohydrate and beta–tricalcium phosphate.

Petersen relates to a bone graft substitute composition consisting of calcium sulfate, a mixing solution and a plasticizing substance.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the HPMC of Petersen within the apatite coated composition of Saito. However as noted above, the "coated solid composition" of Saito is very different from the matrix composition of the subject invention, and combining Saito, Bell and Petersen would in no way arrive at the composition of Claim 18.

Claims 1-4, 6-10, 15, 16, 19, 27, 35, 39 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al U.S. Patent Appln. Pub. 2002/0071827 A1 in view of Bell et al. U.S. Patent Appln. Pub. 2002/0055143 A1. Reconsideration is requested.

Petersen relates to a bone graft substitute composition consisting of calcium sulfate, a mixing solution and a plasticizing substance.

Bell relates to a bone precursor composition comprising a calcium cement which is suitable for injection, wherein said calcium cement includes monobasic calcium phosphate monohydrate and beta–tricalcium phosphate.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the glucosaminoglycans and polysaccharides of Bell within the bone graft substitute compositions of Petersen. There is no discussion in these references alone or in combination of a sustained release matrix having a coating.

3. Response to Double Patenting Rejection

With respect to the double patenting rejections, none of the commonly owned cases relate to a matrix having a coating. Nor is there any suggestion in these references of such a matrix with a coating. As such, the commonly owned cases are not obvious variants of the presently claimed invention so that the double patenting rejection advanced on such a basis is inappropriate and must be withdrawn.

4. Fee Authorization

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

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